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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,088	08/21/2003	Irving Boime	295002005901	1723

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/647,088	BOIME ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-28* is/are pending in the application.

4a) Of the above claim(s) *24 and 26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-23,25,27 and 28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *21-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claims 21-28 are pending.

Applicants election of species wherein β_1 and β_2 are both FSH agonists in the response filed 10/31/2006 is acknowledged. Applicants have identified claims 21-23 and 27-28 as corresponding to the elected species. The Examiner further finds that claim 25 encompasses to the elected species. Accordingly, claims 21-23, 25 and 27-28 are under consideration.

Specification

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim 21 is objected to because of the following informalities: The claim encompasses multiple patentably distinct inventions, namely the non-elected invention, wherein there is a covalent linkage. The claim should be amended to remove the non-elected invention. Appropriate correction is required.

Claims 21-23, 25 and 27-28 are objected to for encompassing non-elected species, there being no allowable generic claim. If allowability of the elected species is determined and the genus remains non-allowable, applicants will be required to amend the claims to limit to the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21-23, 25 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 is indefinite because it has the negative limitation that "if β^1 is CGβ then β^2 is not FSHβ". However, as the two formulae given in the claims are complementary, it is not clear what is excluded, as there is no exclusion that if β^2 is CGβ then β^1 is not FSHβ.

Claim 22 is indefinite for reciting that β^1 and β^2 correspond to different native β subunits; it is not clear whether applicants intend that β^1 and β^2 are FSH subunits from different species of animal, or alternatively whether they are allelic variants, and in either case, whether they are in their 'native' state, or could be "a variant thereof", given that the specification does not breath life and meaning into the term "correspond".

The remaining claims are rejected for depending on an indefinite claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-23, 25 and 27-28 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25-30 of U.S. Patent No. 6,635,256. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive, and the patented claims would form the basis for a rejection under 35 U.S.C. §102 of the pending claims, were it available as prior art. With respect to the limitation of claim 23 that the beta subunits have different half-lives, such would be inherent to a protein in which one beta subunit existed as a fusion protein and the other did not.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Sugihara et al., PNAS 92:2041.

Sugihara synthesized a fusion protein comprising hCG α and β subunits, and administered such to immature female rats, see page 2043, second column. In view of the fact that said rats would also comprise TSH β, LH β and CG β, and that those subunits would spontaneously associate with the fusion protein in vivo, the rats themselves anticipate the claims.

Amendment to indicate that the claimed composition is isolated or purified would overcome this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-23, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over G. De Rosa et al., Annales d'endocrinologie 48(6):468-472, 1987 (Abstract only) in view of R.K. Hyde et al., Biology of Reproduction 54(Suppl. 1) :105, Abstract 193, 1996 and D. Ben-Menahem et al., Abstract OR28-3 presented at Endo 98, Endocrine Society, 1998.

De Rosa et al. report that administration of human menopausal gonadotropins (hMG) was effective in inducing testicular descent in 10 of 20 cases of undescended testes. The Examiner notes that hMG is comprised of FSH and LH.

De Rosa et al. do not teach or suggest administering the FSH and LH by administering a single chain α-β fusion protein with an additional non-covalently linked β subunit.

Hyde et al. teach that coadministration of hCG$\beta\alpha$ and FSHβ results both hCG and FSH activity. Ben-Menahem et al. teach that coadministration of FSH$\beta\alpha$ and hCGβ results in both hCG and FSH activity.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the method of De Rosa et al. by substituting either the coadministration of either LH$\beta\alpha$ and FSHβ or the coadministration of FSH$\beta\alpha$ and LHβ, in view of the teachings of Hyde et al. and Ben-Menahem et al. that co-administration of a single-chain glycoprotein hormone fusion protein with an additional β subunit is effective for producing both activities in the treated patient. One of ordinary skill in the art would have been motivated to do so to obtain the known an expected properties of having both FSH and LH activity as taught by De Rosa et al., and would have expected success because of the teachings of both Hyde et al. and Ben-Menahem et al. that such co-administration results in both activities. Accordingly, the invention, taken as a whole, is *prima facie* obvious over the prior art.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Duijkers et al.,(., " Follicular fluid hormone concentrations after ovarian stimulation using gonadotropin preparations with different FSH/LH ratios. I. Comparison of an FSH-dominant and a purified FSH preparation." International journal of fertility and women's medicine (UNITED STATES) Sep-Oct 1997, 42 (5) p306-10 (Abstract only).), teach that: "Human menopausal gonadotropin (hMG) contains equal amounts of FSH and LH activity".

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner